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(54) **BALLOON EXPANDABLE PLATFORM WITH RETAINING FEATURES FOR A COLLAPSIBLE VALVE**

(75) Inventors: **Aaron J. Chalekian**, Minneapolis, MN (US); **Daniel J. Klima**, Andover, MN (US); **Cherry L. Knight**, New Hope, MN (US); **Jane M. Korfe**, Buffalo, MN (US); **Trevor C. Knight**, Minnetonka, MN (US)

(73) Assignee: **St. Jude Medical, Cardiology Division, Inc.**, St. Paul, MN (US)

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A61F 2/958	(2013.01)
A61M 25/10	(2013.01)

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CPC ***A61F 2/2433*** (2013.01); ***A61F 2/958*** (2013.01); *A61F 2002/9583* (2013.01); *A61F 2002/9586* (2013.01); *A61M 2025/1086* (2013.01)

(58) **Field of Classification Search**
CPC ... A61F 2002/9583; A61F 2/95; A61F 2/958; A61F 2/2433; A61M 2025/1086
USPC 623/1.11; 606/194
See application file for complete search history.

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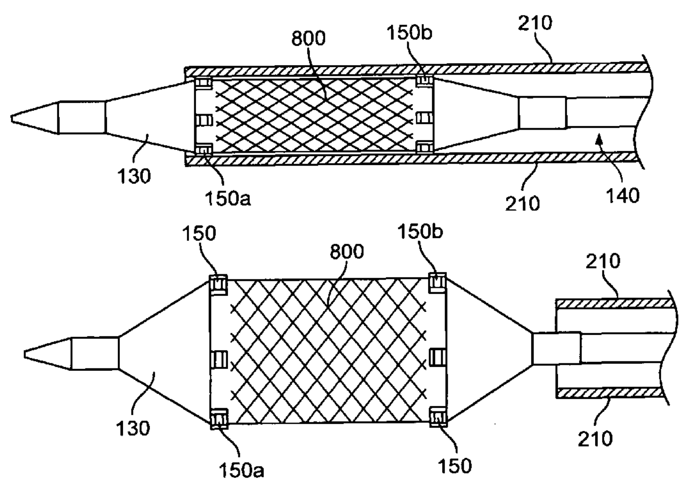
Primary Examiner — Sarah W Aleman
(74) *Attorney, Agent, or Firm* — Lerner, David, Littenberg, Krumholz & Mentlik, LLP

(57) **ABSTRACT**

Retainer structures (**150**) maintain stented valves (**800**) on the balloon (**130**) of a balloon catheter during delivery of the valve to an implantation node and subsequent expansion of the valve. The retainer structures define a raised edge relative to the outer surface of the balloon and limit movement of the valve longitudinally relative to the balloon. Deflation of the balloon following expansion of the valve stent releases the valve.

13 Claims, 7 Drawing Sheets



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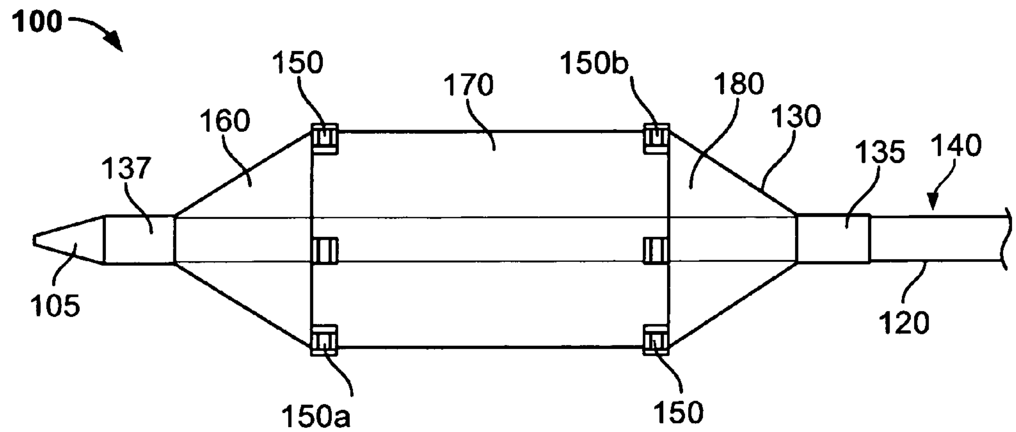

FIGURE 1

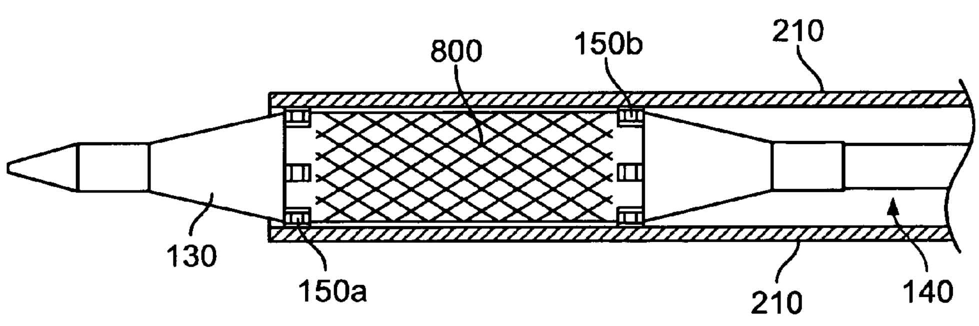

FIGURE 2A

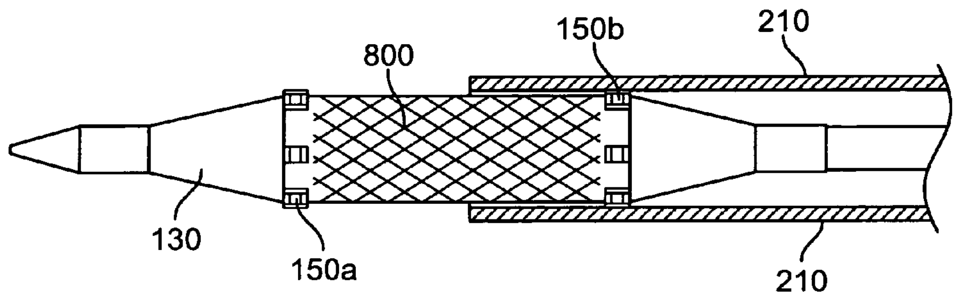

FIGURE 2B

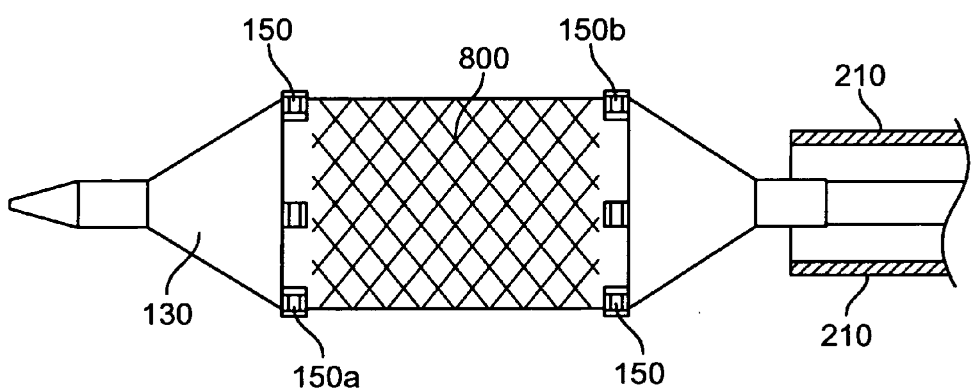

FIGURE 2C

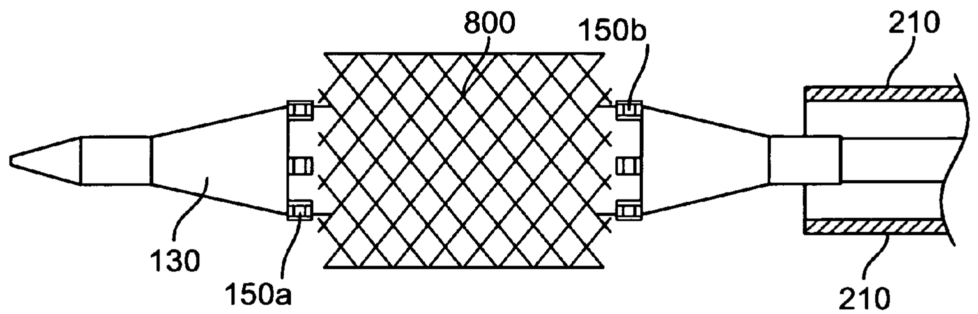

FIGURE 2D

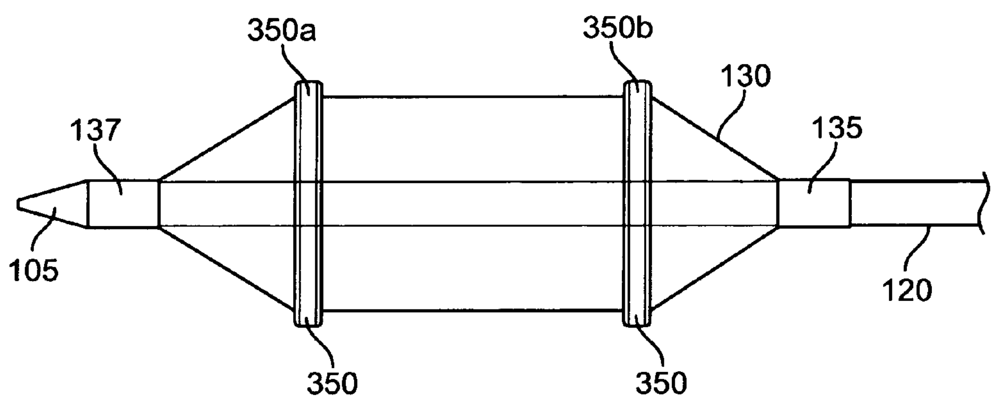

FIGURE 3

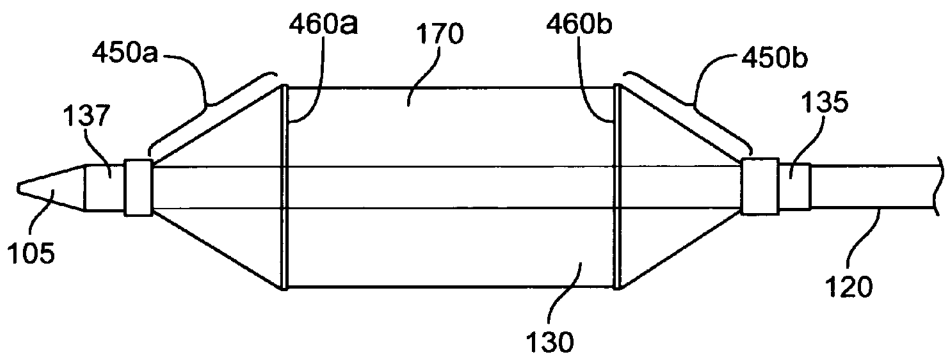

FIGURE 4

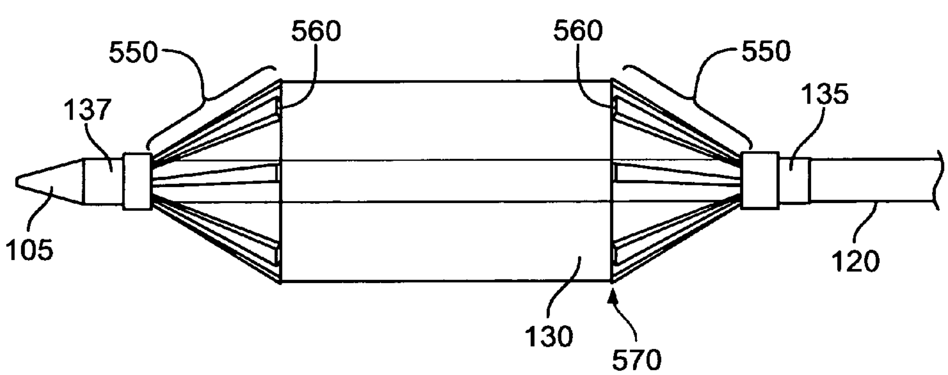

FIGURE 5

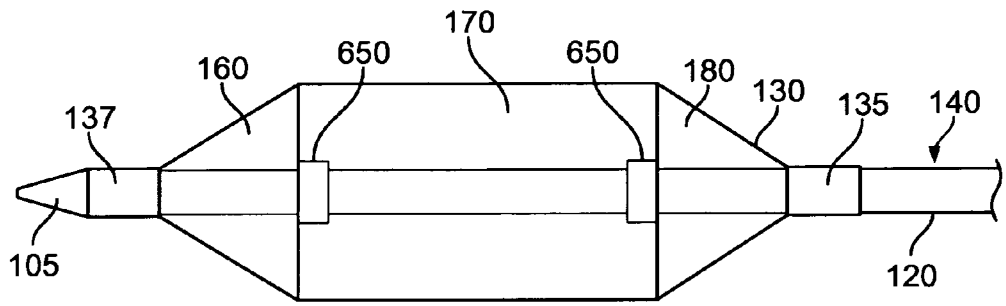

FIGURE 6

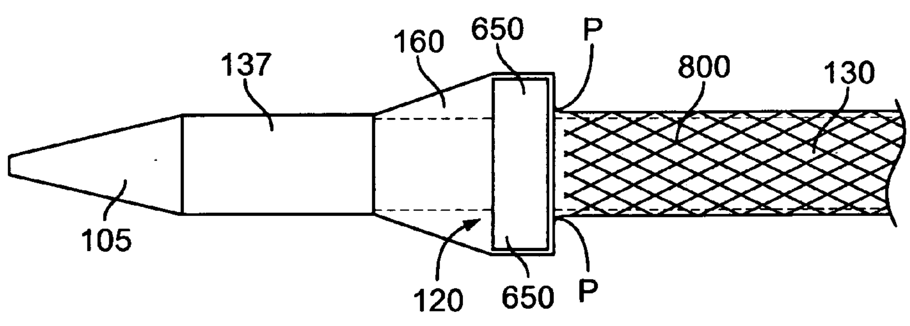

FIGURE 7

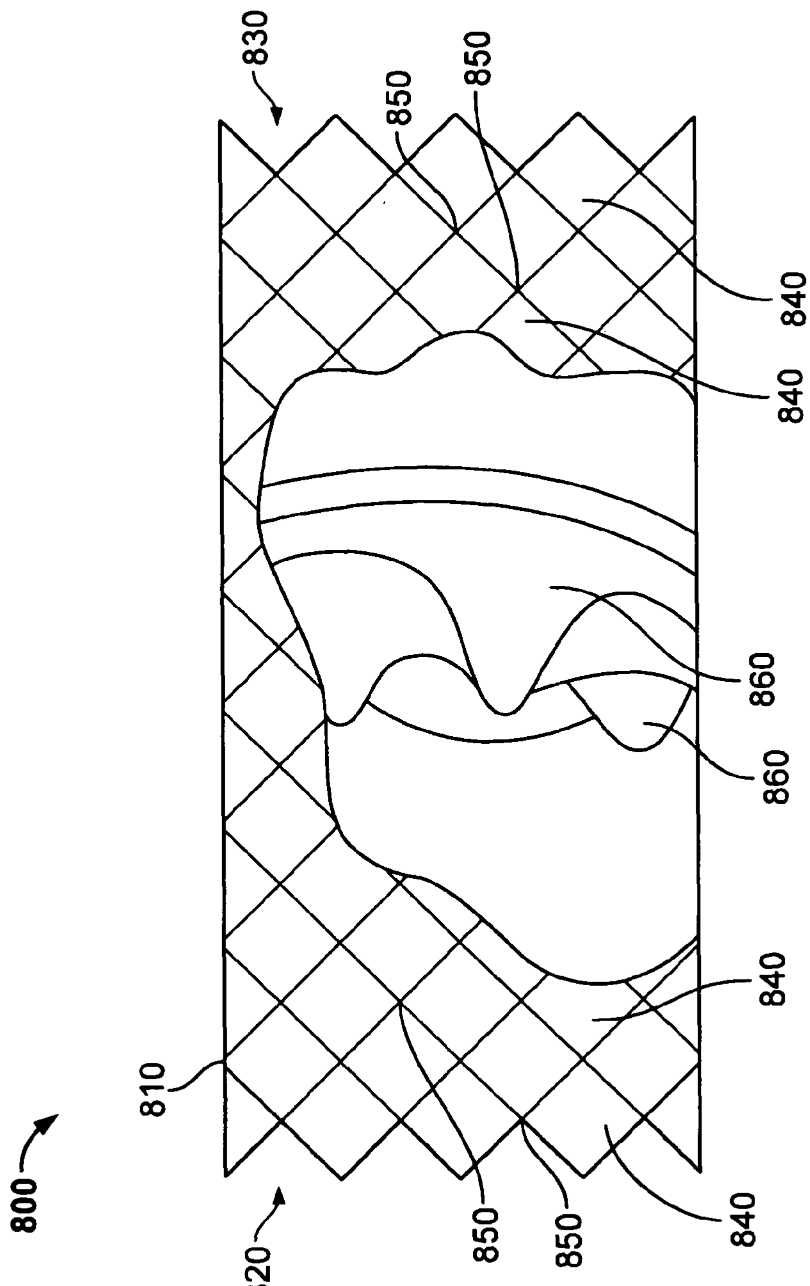

FIGURE 8

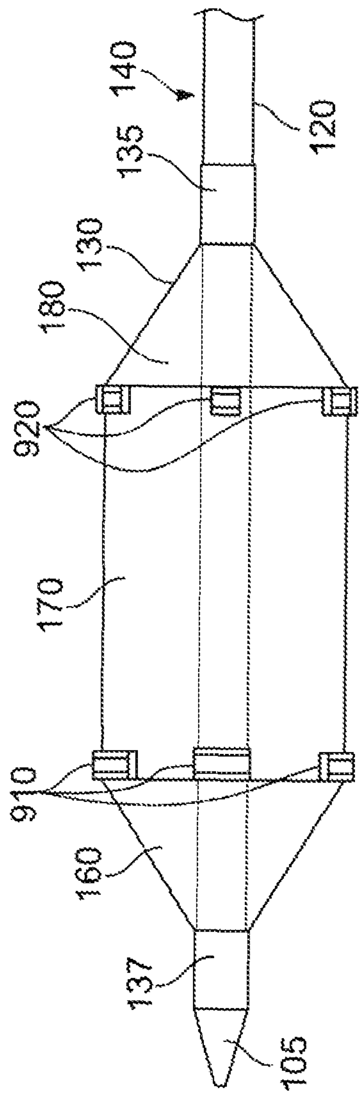

FIGURE 9

BALLOON EXPANDABLE PLATFORM WITH RETAINING FEATURES FOR A COLLAPSIBLE VALVE

CROSS-REFERENCE TO RELATED APPLICATION

The present application is a national phase entry under 35 U.S.C. §371 of International Application No. PCT/US2011/000892 filed May 19, 2011, published in English, which claims priority from U.S. Provisional Application No. 61/346,175, filed May 19, 2010, all of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

The present invention relates to collapsible prosthetic valves for use in heart valve repair. More particularly, the invention relates to methods and apparatus used to deploy balloon-expandable prosthetic valves.

Damaged or weak heart valves may require replacement with prosthetic valves. While prosthetic valves typically have been implanted using surgical procedures, recent developments in this area have led to prosthetic valves which are capable of implantation using minimally invasive techniques. One such technique employs valves supported by stents. Such valves may typically be collapsed into a compressed state for transluminal delivery to the desired location and then expanded in vivo for final placement. Devices for delivering these valves, such as catheter-based delivery devices, may be used to insert the valve through a body lumen of a human or animal, position the valve, release the valve within the body lumen, and, where necessary, expand the diameter of the valve to hold it in place in the body lumen.

Prosthetic valves may be self-expanding or may employ some other method, such as the application of heat or the inflation of one or more balloons, to facilitate expansion. Balloon expansion employs a catheter having a balloon which is inflated to expand the valve into the non-compressed state. Such balloons may be inflated by various methods, including providing gases or liquids to fill the interior space of the balloon. The balloon may subsequently be deflated to release the valve and to enable the balloon catheter to be withdrawn from the body.

In a typical balloon inflation arrangement, a prosthetic valve may be assembled over the uninflated balloon of a balloon catheter and then collapsed to a relatively small diameter, or may be slid over the uninflated balloon while collapsed to the relatively small diameter. A sheath of the catheter may then be positioned over the valve to hold it in place and maintain it in the collapsed condition. Once the catheter has been positioned at the desired location, the sheath may be removed, revealing the uninflated balloon and collapsed valve. The balloon may subsequently be inflated to expand the valve stent into contact with the body lumen. Once the valve has been properly placed and the valve stent fully expanded, the balloon may be deflated and the delivery catheter removed from the patient.

After removal of the sheath and prior to inflation of the balloon, several factors may make accurate positioning of the valve within the body lumen difficult. In particular, forces, such as the vibrations of a beating heart and the high velocity of blood flow within and immediately adjacent to the heart, create a turbulent environment which could cause the valve to move relative to the balloon during this time period. For example, the aforementioned forces may increase the likelihood that the valve will move longitudinally along the balloon. It will be appreciated that accurate location and expansion of the prosthetic valve is critical to the proper functioning of the valve. For example, if the valve were to move longintudinally relative to the balloon prior to balloon inflation, the valve may not be positioned in the correct location within the body lumen. Further, if the valve were to move so that the full length of the valve stent does not overlie the balloon when the balloon is inflated, the full length of the valve stent may not be expanded and the valve may not be securely held in place. Therefore, there exists a need for a device which will accurately maintain the position of the valve relative to the balloon during the deployment process.

SUMMARY OF THE INVENTION

One aspect of the present invention provides a delivery system for a prosthetic valve having a valve structure mounted to a stent structure. The stent structure may have a collapsed condition and an expanded condition. In the collapsed condition the stent may have a length between a first end and a second end.

The delivery system may also include a balloon extending in a longitudinal direction. The balloon has a first end portion, a second end portion, and a middle portion between the first end portion and the second end portion. The middle portion of the balloon has an outer surface with a first diameter in an inflated condition and a second diameter in a deflated condition. An inflation lumen may be connected in fluid communication to an interior of the balloon for supplying an inflation fluid to the balloon.

The delivery system may also include first and second retainer structures. Each of the retainer structures may define a raised edge relative to the outer surface of the middle portion. The raised edges may be spaced apart in the longitudinal direction to define a receiving space around the middle portion of the balloon. The receiving space may have a length in the longitudinal direction which is greater than the length of the stent structure in the collapsed condition. The entire length of the stent structure in the collapsed condition may be receivable in the receiving space. The raised edges may limit movement of the stent structure in the longitudinal direction relative to the balloon.

The first retainer structure may be of a type selected from the group consisting of a node, a ring, a skirt, and a fan skirt. The second retainer structure may be of a type selected from the group consisting of a node, a ring, a skirt, and a fan skirt. The first retainer structure may also be of a first type and the second retainer structure is of a type different from the first type. Alternatively, the first retainer structure may be of a first type and the second retainer structure may also be of the first type.

The raised edges may be positioned relative to the middle portion to limit movement of the stent structure in the longitudinal direction relative to the balloon when the balloon is in the inflated condition and the stent is in the expanded condition. The raised edges may be positioned relative to the middle portion to limit movement of the stent structure in the longitudinal direction relative to the balloon during inflation of the balloon from the deflated condition to the inflated condition. The raised edges may be sized and shaped to release the valve structure upon deflation of the balloon from the inflated condition.

Another aspect of the invention provides a method of delivering a prosthetic valve to an implantation site. The prosthetic valve may have a valve structure mounted to a stent structure. The stent structure may have a collapsed condition, an expanded condition, and a length in the collapsed condition between a first end and a second end. The method may include assembling the valve around a balloon having an inflated condition and a deflated condition. The balloon may extend in a longitudinal direction. The balloon may have an outer surface and first and second retainer structures each defining a raised edge relative to the outer surface. The raised edges may be spaced apart in the longitudinal direction to define a receiving space around the outer surface of the balloon. The receiving space may have a length in the longitudinal direction which is greater than the length of the stent structure in the collapsed condition. The valve may be assembled in the receiving space so that the stent structure is in the collapsed condition and the balloon is in the deflated condition.

The method may also include covering the valve in the collapsed condition and the balloon in the deflated condition with a sheath. The covered valve and balloon may be moved to an implantation site. The sheath may be removed from over the valve and the balloon to expose the valve and the balloon, whereby the valve is held in the receiving space and the raised edges limit movement of the stent structure in the longitudinal direction relative to the balloon. The balloon may be inflated to the inflated condition, whereby the stent structure of the valve is expanded to the expanded condition. The balloon may also be deflated to the deflated condition, and the deflated balloon may be removed from the stent structure.

The raised edges may limit movement of the stent structure in the longitudinal direction relative to the balloon when the balloon is in the inflated condition. The deflating step may release the stent structure from the receiving space so that the raised edges no longer limit movement of the stent structure in the longitudinal direction relative to the balloon. The removing step may include withdrawing the retainer structures through a lumen of the stent structure.

The first retainer structure may be of a type selected from the group consisting of a node, a ring, skirt, and a fan skirt. The second retainer structure may be of a type selected from the group consisting of a node, a ring, a skirt, and a fan skirt. The first retainer structure may be of a first type and the second retainer structure is of a type different from the first type. Alternatively, the first retainer structure is of a first type and the second retainer structure is of the first type.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a partial side elevational view of a delivery catheter with an expanded balloon having a retaining mechanism in accordance with a first exemplary embodiment of the invention.

FIGS. **2**A-**2**D are partial side elevational views showing a delivery method using the delivery catheter of FIG. **1**.

FIG. **3** is a partial side elevational view of a delivery catheter with an expanded balloon having a retaining mechanism in accordance with a second exemplary embodiment of the invention.

FIG. **4** is a partial side elevational view of a delivery catheter with an expanded balloon having a retaining mechanism in accordance with a third exemplary embodiment of the invention.

FIG. **5** is a partial side elevational view of a delivery catheter with an expanded balloon having a retaining mechanism in accordance with a fourth exemplary embodiment of the invention.

FIG. **6** is a partial side elevational view of a delivery catheter with an expanded balloon having a retaining mechanism in accordance with a fifth exemplary embodiment of the invention.

FIG. **7** is a partial side elevational view of a delivery catheter with an at least partially unexpanded balloon having a retaining mechanism in accordance with the fifth exemplary embodiment of the invention.

FIG. **8** is a highly schematic side elevational view of a stented valve, partially broken away to show the valve leaflets in the interior thereof.

FIG. **9** is a partial side elevation view of a delivery catheter with an expanded balloon having a retaining mechanism in accordance with a sixth exemplary embodiment of the invention.

DETAILED DESCRIPTION

The present invention is directed to mechanisms for retaining a collapsible stented valve in place on a balloon catheter during a valve deployment procedure. Such mechanisms may include retaining structures which prevent or block the movement of the valve stent axially along the catheter balloon before the balloon has been fully inflated. The retaining structures may take various forms, including bulges, nodes, rings, skirts, or fans, and any combination of such forms. In some embodiments, when the balloon is fully inflated, each retaining structure may maintain its shape, preventing the valve stent from moving in the axial direction along the balloon. The valve may then be released upon deflation of the balloon. In some embodiments, the valve may be maintained in a position by a retaining structure as well as by the balloon during inflation, while in other embodiments, after initial expansion, the valve may be maintained in a position by only the balloon.

The present invention may be used in connection with any suitable balloon-expandable stented valve. As presently known, and as depicted in FIG. **8**, a conventional stented valve **800** includes a generally cylindrical stent **810** having a first end **820** and a second end **830**, with a plurality of leaflets **860** supported within the stent. A plurality of interconnected struts **850** define cell structures **840** which enable stent **810** to collapse from the fully expanded diameter shown in the figure to a smaller collapsed diameter. In one example, struts **850** may be formed from a plurality of interconnected wires. In another example, the struts may be formed from a preformed tube which is cut to form the cell structures **840**. Stent **810** may be formed from any biocompatible material that may be plastically deformed and that will retain its deformed shape.

Valve leaflets **860** may be formed from natural tissue, either human or animal, or from artificial materials, including polymers. Commissure posts and/or other stent structures may support valve leaflets **860** within stent **810**.

The stent valves to which the present invention pertains may have a diameter of about 19 mm to about 27 mm when expanded for use in a body lumen. Such diameters may provide room for the valve within the stent and may also permit the stent valve to be held in place within the native valve architecture.

The valve may comprise two or more leaflets which alternate between open and closed positions with the change in flow pressure of blood. In particular, the leaflets may function as one-way check valves that open to allow blood flow in a desired direction. The leaflets may also close in response to pressure differentials in order to limit reverse flow. Thus, when blood is flowing downstream, the leaflets may fully open to allow for flow through the valve. The leaflets may also correspondingly close to inhibit flow upstream. For aortic and pulmonary valves, the valves may open to permit blood flow from the heart into the arteries and may close to resist flow back from the arteries to the heart.

Stent **810** may be inserted into the body, moved to a deployment site, and deployed using a delivery catheter, such as a balloon catheter. The distal end of one such balloon catheter **100** is shown in FIG. **1**. Catheter **100** includes a balloon **130** which is connected to catheter body **140** at a proximal seal **135** and a distal seal **137**. The balloon **130** may be connected to catheter body **140** by any known method, for example, by chemical or mechanical welding to the proximal and distal seals **135**, **137**. Although not completely depicted in FIG. **1**, catheter body **140** may extend from a distal tip **105** to a proximal end which remains outside of the body. The proximal end may be connected to a liquid source, such as an incompressible liquid with a radiopaque contrast, for inflating the balloon. Distal tip **105** may also be tapered to help guide catheter **100** through a body lumen to the deployment site.

Balloon **130** is shown in FIG. **1** in a fully inflated or expanded condition. However, during the insertion of catheter **100**, balloon **130** is in an uninflated or collapsed condition. Balloon **130** may be placed in the collapsed condition (not shown) by folding the balloon in any manner, for example, using a pleat fold or a T-fold. Balloon **130** may have a first tapered end portion **160**, a middle portion **170**, and a second tapered end portion **180**, all of which can be readily seen in the expanded condition of FIG. **1**.

As noted above, catheter **100** may be used to deploy prosthetic valves including stents having fully expanded diameters of up to about 30 mm. Once the balloon is deflated, the stent may recoil a few millimeters, for example 1-2 mm. Thus, the stent may actually be slightly smaller after being implanted. Accordingly, a stent expanded to about 30 mm may recoil to about 27 mm. Accordingly, to fully expand these valve stents into firm engagement with structures in and around the heart, balloon **130** may expand to a diameter of up to about 30 mm.

In its fully expanded condition, the middle portion **170** of balloon **130** may have a generally cylindrical cross-section, although other cross-sectional shapes are contemplated, including triangular, rectangular, trapezoidal, elliptical, curved, and other polygonal and non-polygonal shapes.

Stented valve **800** is assembled over balloon **130** for delivery. In one example, stented valve **800** in the expanded state may be positioned over the middle portion **170** of balloon **130** with the balloon in the uninflated or collapsed condition. Stented valve **800** may subsequently be collapsed into a compressed form around balloon **130**. Various methods may be employed to collapse stented valve **800** around the balloon, such as hand tools or other mechanical or chemical methods. In another example, stented valve **800** may be at least partially collapsed prior to assembly over balloon **130**. The at least partially collapsed valve may be maneuvered over the distal end **105** of balloon catheter **100** and positioned over middle portion **170** of balloon **130**. The partially collapsed stented valve may then be further collapsed around the balloon.

Once the stented valve has been assembled over balloon **130** and placed in the collapsed condition, a sheath, such as sheath **210** of FIG. **2**A, may be moved into position over the assembly. Sheath **210** may protect stented valve **800** and balloon **130** during the insertion of catheter **100** into and through the patient's vasculature, and at the same time prevent displacement of the valve relative to the balloon.

Once catheter **100** has been positioned at or near the native valve where stented valve **800** is to be implanted, sheath **210** may be withdrawn to reveal stented valve **800** and balloon **130**. As noted above, after removal of the sheath **210** and prior to inflation of the balloon **130**, various forces, such as the vibrations of a beating heart and the high velocity of blood flow within and immediately adjacent to the heart, may cause the valve to move relative to the balloon.

In order to retain stented valve **800** in its assembled position on balloon **130** once sheath **210** has been withdrawn, balloon **130** may be provided with a plurality of raised retainer nodes **150**. As shown in FIG. **1**, a first group of one or more retainer nodes **150***a* may be positioned at one end of the middle portion **170** of balloon **130**, and a second group of retainer nodes **150***b* may be positioned at the other end of middle portion **170**. Where each end of middle portion **170** includes more than one retainer node **150**, the retainer nodes may be spaced either evenly or unevenly around the outer circumference of the middle portion.

It will be appreciated that retainer node groups **150***a* and **150***b*, shown in FIG. **2**A, do not have to be at the ends of middle portion **170**. Rather, they may be spaced apart in the longitudinal or axial direction of balloon **130** by a distance sufficient to accommodate the stent **810** of stented valve **800** fully therebetween. In that regard, node groups **150***a* and **150***b* may be spaced apart in the longitudinal direction so as to contact the ends of stent **810** in the collapsed condition and substantially prevent the stent from moving in the longitudinal direction relative to balloon **130**. Alternatively, node groups **150***a* and **150***b* may be spaced apart by a distance greater than the length of stent **810** in the collapsed condition so that the stent may be free to move by a relatively small amount in the longitudinal direction in relation to balloon **130**. While limiting movement in the longitudinal direction, the retainer nodes are not positioned in the stent cells **840** and therefore do not interfere with the full collapsing of the stent. Moreover, because of this positioning, the retainer nodes may allow the stent in the collapsed or expanded conditions to rotate on the balloon.

Nodes **150** may be of various shapes and sizes and may be either mounted to the outer surface of balloon **130** or formed integrally with the balloon, for example in a molding process with the balloon. Other examples of the formation of the retainer nodes may include a separate molding operation after the formation of the balloon, bonding the retainer nodes to the balloon surface, or a process commonly referred to as balloon grinding. Nodes **150** may be characterized as bumps, humps, raised protrusions, angular projections, or the like. As shown in FIG. **9**, the size and shape of the nodes in one group, group **910**, may be the same as or different from the size and shape of the nodes in the other group, group **920**. Also, the nodes in one group need not all be of the same size and shape, but may be specifically sized and shaped relative to any features which may be present at the ends of stent **810**. In all cases, however, nodes **150**, both individually and collectively, define raised edges relative to the outer surface of the middle position **170** of the balloon that engage the free ends of stent **810** and limit the movement of valve **800** in the longitudinal direction relative to the balloon **130**.

Nodes **150** may be generally rigid such that the nodes may protrude from the balloon regardless of whether the balloon is in a collapsed condition or an expanded condition. As balloon **130** expands, nodes **150** may move with the balloon and maintain their general form. When the balloon **130** is fully inflated, as shown in FIG. **1**, the nodes **150** may continue to maintain their form, holding stent **810** in place therebetween. Once stent **810** has been properly positioned and fully expanded, it may be released from balloon **130** by deflating the balloon. As balloon **130** collapses, the balloon and nodes **150** may be withdrawn through the expanded stent **810** and valve leaflets **860**.

FIGS. **2**A-**2**D depict an exemplary expansion of stented valve **800** using a balloon catheter **100** in which the balloon

130 includes retainer nodes **150**. As shown in FIG. **2**A, stented valve **800** is positioned on the balloon **130** such that the valve stent **810** is substantially centered on the middle portion **170** of the balloon and positioned axially between retainer nodes **150**. Sheath **210** extends over the balloon **130** and stented valve **800** and prevents them from being subjected to forces that may change their relative positions. When catheter **100** has been advanced to a location in which stented valve **800** is substantially at the desired position in the body for deployment, sheath **210** may be withdrawn from its position over stented valve **800** and balloon **130** as depicted in FIG. **2**B. Despite the turbulence and other movement artifacts to which stented valve **800** may be subjected at this point in the deployment, retainer nodes **150** may hold the valve securely in position on the uninflated balloon **130**.

Once the accurate positioning of stented valve **800** has been confirmed, balloon **130** may be inflated, expanding stent **810** into a non-compressed geometry. As balloon **130** expands, retainer nodes **150** move radially outward with the balloon while continuing to project outwardly from the balloon surface. Hence, when balloon **130** has been fully inflated, retainer nodes **150** may still maintain the longitudinal position of stented valve **800** relative to the balloon and provide protection for the ends of valve stent **810**. Therefore, as long as balloon catheter **100** is held firmly in place during valve deployment, the position of stented valve **800** will remain substantially unchanged and the valve will be deployed in the proper location. When deployment has been completed, balloon **130** may be deflated as shown in FIG. **2**D and catheter **100** may be withdrawn from stented valve **800**, leaving the valve in place.

A retaining mechanism in accordance with a second embodiment of the present invention is shown in FIG. **3**. The embodiment of FIG. **3** is substantially the same as the embodiment of FIG. **1** described above, except that retainer nodes **150** have been replaced with retainer rings **350**. Similar to the function of retainer nodes **150**, retainer rings **350** may form retainers which maintain their general form during the inflation of balloon **130** and prohibit movement of stented valve **800** longitudinally along the balloon prior to and during inflation.

Retainer rings **350** may be placed at each end of the middle portion **170** of balloon **130** to maintain the general position of the stented valve **800** along the balloon. As with nodes **150**, retainer rings **350*a*** and **350*b***, shown in FIG. **3**, do not have to be at the ends of middle portion **170**, but may be spaced apart by a distance sufficient to accommodate the stent **810** of stented valve **800** fully therebetween. In that regard, the distance between retainer rings **350*a*** and **350*b*** may be such that they either contact or do not contact the ends of stent **810**, allowing little or no movement of the valve in relation to the balloon. As with nodes **150**, the retainer rings do not interfere with the full collapsing of stent **810** and may allow the collapsed stent to rotate on the balloon.

Retainer rings **350*a*** and **350*b*** may be formed similarly to nodes **150** described above. For example, a ring may be mounted to the outer surface of balloon **130** or formed integrally with the balloon in a molding or grinding process. Retainer rings **350*a*** and **350*b*** may protrude above the surface of balloon **130** at the same or different heights depending on the requirements of stent **810**. Further, the axial or circumferential thickness of each retainer ring **350*a*** and **350*b*** may be constant around balloon **130** or may vary to accommodate certain features of stent **810**. In all cases, however, retainer rings **350*a*** and **350*b*** present raised edges which engage the ends of stent **810** and limit its movement in the longitudinal direction relative to the balloon.

As noted above, retainer rings **350** may expand elastically and continue to project outwardly from balloon **130** as the diameter of the balloon increases during inflation. When the balloon is fully inflated, as shown in FIG. **3**, the rings **350** may continue to protrude from the surface of the balloon, providing end protection to stent **810** and maintaining the axial position of stented valve **800** on the delivery catheter. Once stented valve **800** has been deployed within the body lumen and fully expanded, balloon **130** may be deflated, allowing the valve to be released from the delivery catheter. The delivery catheter may be removed by withdrawing the balloon **130** and retainer rings **350** through the valve leaflets **860** and stent **810**.

A retaining mechanism in accordance with a third embodiment of the present invention is shown in FIG. **4**. In this embodiment, rather than nodes or rings on the circumference of middle portion **170** as in the previously described embodiments, balloon **130** is provided within a retainer skirt **450*a*** or **450*b*** on each of balloon end portions **160** and **180**. Retainer skirts **450*a*** and **150*b*** may expand elastically during inflation of balloon **130** and continue to project outwardly from the balloon as the diameter of the balloon increases during inflation. A first skirt **450*a*** on end portion **160** may protrude above the surface of the middle portion **170** to define an annular edge or lip **460*a*** at one end of the middle portion. A second skirt **450*b*** may protrude above the surface of the middle portion **170** to define an annular edge or lip **460*b*** at the other end of the middle portion. As with the previous embodiments, lips **460*a*** and **460*b*** are spaced apart a sufficient distance to receive the stent **810** of stented valve **800** therebetween. Thus, lips **460*a*** and **460*b*** cooperate to maintain the position of stent **800** relative to balloon **130**.

Similar to retainer nodes **150** and retainer rings **350**, retainer skirts **450*a*** and **450*b*** may be separately formed and mounted to end portions **160** and **180**, respectively, or may be formed by making the thickness of balloon **130** greater in end portions **160** and **180** than in middle portion **170**. This increased thickness may be uniform from the proximal and distal seals **135**, **137** to the middle portion **170**. Alternatively the thickness may increase gradually from the seals **135**, **137** toward the middle portion. Retainer skirts **450*a*** and **450*b*** may also be of different thicknesses and accordingly lips **460*a*** and **460*b*** may protrude above the balloon **130** at different radial distances circumferentially around the balloon.

Lips **460*a*** and **460*b*** may be positioned at each end of the middle portion of balloon in order contact or not contact the ends **820**, **830** of the stented valve **800**. Accordingly, lips **460*a*** and **460*b*** may prevent any axial movement relative to the balloon **130** or provide for only some small movement. Lips **460*a*** and **46-*b*** may function similarly to retainer nodes **150** and retainer rings **350**, protruding outwardly from the balloon prior to and during inflation of the balloon and accordingly, providing end protection to the stent and preventing longitudinal movement of the stented valve **800** relative to the balloon **130**. Again, once the stented valve **800** is fully expanded and positioned within the body lumen, the balloon may be deflated, and the catheter **100** removed through the valve leaflets **860** and stent **810**.

A retaining mechanism in accordance with a fourth embodiment of the present invention is shown in FIG. **5**, in which retainer fan skirts **550** are provided. The retainer fan skirts **550** operate similarly to retainer nodes **150**, retainer rings **350**, and retainer skirts **450*a*** and **450*b*** described above, in that they may also be used to maintain the position of the valve on the delivery catheter prior to and during inflation of the balloon.

Retainer fan skirts **550** preferably comprise one or more ridges **560**. Similar to the embodiments described above, ridges **560** may be mounted to or formed from the balloon material and may be evenly or unevenly spaced around the circumference of balloon **130** and of various shapes and sizes. Two or more ridges within the same fan skirt may have different shapes and thicknesses. Accordingly, if more than one retainer fan skirt **550** is used, the skirts may have different shapes and dimensions.

Ridges **560** may extend from the proximal and distal seals **135** and **137** to the middle portion **170**. Ridges **560** may also continue along some length of the middle portion **170** and terminate in protruding bumpers **570** which may both provide end protection to the stent and prevent or limit longitudinal movement of the stented valve **800** relative to the balloon. Ridges **560** may terminate such that the bumpers are positioned along the balloon **130** to contact both ends **820**, **830** of the stented valve **800** and prohibit any movement of the stented valve **800** in the longitudinal or axial direction along the balloon. The bumpers **570** may also terminate so as to contact one end or neither end of the stented valve **800**, and therefore allow limited longitudinal movement of the stented valve **800** relative to the balloon **130**. Nonetheless, the ridges **560** do not interfere with the full collapsing of the stent **810** and may allow the collapsed stent to rotate on the balloon.

As the balloon **130** is inflated, the retainer fan skirts **550** may expand with the balloon and both the ridges **560** and bumpers **570** may continue to protrude above the surface of the balloon. When the balloon **130** is fully inflated, as shown in FIG. **5**, the bumper protrusions **570** may continue to maintain the general position of the valve on the delivery catheter. Finally, once in position, the valved stent **800** may be released by deflating the balloon **130**, and the catheter **100** may be removed through the stent **810** and the valve leaflets **860**.

A retaining mechanism in accordance with a fifth embodiment of the present invention is shown in FIG. **6**. In this embodiment, retainer bulges **650** may be used to maintain the position of the valved stent relative to the balloon **130** prior to and during expansion of the balloon.

As shown in FIG. **6**, two retainer bulges **650** may be positioned at each end of the middle portion **170** of the balloon **130**. The retainer bulges **650** may be integrated on the inner lumen **120** of the delivery device by thermal or adhesive bonding. When mounted to the inner lumen **120**, bulges **650** may be rigid, and may maintain their general configuration before and during inflation. In an alternative, retainer bulges **650** may be mounted to or formed on an inner surface of balloon **130**. The retainer bulges may be elastic so as to expand as the balloon is expanded. The retainer bulges **650** may be configured of any material, for example, metal or plastic, but are preferably a polymer.

As shown in FIG. **7**, the valved stent **800** may be placed along the uninflated balloon **130** to contact the balloon material between the stented valve **800** and the retainer bulge **650** at a pinch point P. As the balloon expands, retainer bulges **650** may maintain the position of the stent by prohibiting any or substantially all movement of the stented valve **800** in the longitudinal or axial direction along the balloon until the expanded diameter of the balloon is greater than the diameter of the retainer bulge. At this point, the stented valve **800** may have also expanded to a diameter greater than the diameter of the retainer bulge so as to no longer be retained between the bulges. The stented valve **800** may continue to be expanded by the balloon **130** and placed in position against the body lumen. Balloon **130** may be deflated and catheter **100** may be removed through the stent **810** and the valve leaflets **860**. It will be appreciated that, as with the other embodiments described above, the retainer bulges **650** do not interfere with the full collapsing of the stent **810** on the balloon, and may allow the collapsed stent to rotate on the balloon.

Most of the foregoing alternative embodiments are not mutually exclusive, but may be implemented in various combinations to achieve unique advantages. For example, one end of the balloon may include a particular retainer arrangement while the other includes a second. As these and other variations and combinations of the features discussed above can be utilized without departing from the invention as defined by the claims, the foregoing description of the embodiments should be taken by way of illustration rather than by way of limitation of the invention as defined by the claims. It will also be understood that the provision of examples of the invention (as well as clauses phrased as "such as," "including" and the like) should not be interpreted as limiting the invention to the specific examples; rather, the examples are intended to illustrate only one of many possible embodiments.

The invention claimed is:

1. A delivery system for a prosthetic valve, the delivery system comprising:

a valve structure mounted to a stent structure, the stent structure having a collapsed condition, an expanded condition, and a length in the collapsed condition between a first end and a second end;

a balloon extending in a longitudinal direction and having a first tapered end portion, a second tapered end portion and a middle portion between the first tapered end portion and the second tapered end portion, the middle portion having an outer surface with a first diameter in a fully inflated condition and a second diameter in a deflated condition;

an inflation lumen connected in fluid communication to an interior of the balloon for supplying an inflation fluid to the balloon; and,

first and second retainer structures attached to an outer surface of only the middle portion, each of the first and second retainer structures defining a raised edge relative to the outer surface of the middle portion, the raised edges being spaced apart in the longitudinal direction to define a receiving space around the middle portion of the balloon, the receiving space having a length in the longitudinal direction which is greater than the length of the stent structure in the collapsed condition so that the entire length of the stent structure in the collapsed condition is receivable in the receiving space,

wherein the raised edges allow for limited movement of the stent structure in the longitudinal direction relative to the balloon both when the stent structure is in the collapsed condition and the balloon is in the deflated condition and when the stent structure is in the expanded condition and the balloon is in the fully inflated condition, the raised edges being configured to maintain their shape when the balloon is inflated from the deflated condition to the fully inflated condition, and

wherein the raised edges are configured to no longer limit movement of the stent structure in the longitudinal direction relative to the balloon after the balloon is deflated from the fully inflated condition to the deflated condition and the stent structure is in the expanded condition, and the first retainer structure is of a first type and the second retainer structure is of a second type different from the first type.

2. The delivery system of claim **1**, wherein the first retainer structure is of a type selected from the group consisting of a node, a ring, a skirt, and a fan skirt.

3. The delivery system of claim **2**, wherein the second retainer structure is of a type selected from the group consisting of a node, a ring, a skirt, and a fan skirt.

4. The delivery system of claim **1**, wherein the raised edges are positioned relative to the middle portion to limit movement of the stent structure in the longitudinal direction relative to the balloon during inflation of the balloon from the deflated condition to the inflated condition.

5. The delivery system **1**, further comprising:

a first group of retainer structures of the first type defining raised edges at a first end of the receiving space, wherein the first retainer is included in the first group; and

a second group of retainer structures of the second type defining raised edges at a second end of the receiving space opposite of the first end of the receiving space, wherein the second retainer is included in the second group.

6. The delivery system of claim **5**, wherein the first group of retainers are of a first type of node having a first size and a first shape, and the second group of retainers are of a second type of node having a second size different from the first size, the second type of node having a second shape different from the first shape.

7. The delivery system of claim **5**, wherein the first group of retainers include nodes that are not all of a same size and shape.

8. The delivery system of claim **1**, wherein the raised edges are configured to allow for rotational movement of the stent structure in the collapsed condition.

9. A method of delivering a prosthetic valve to an implantation site, the prosthetic valve having a valve structure mounted to a stent structure, the stent structure having a collapsed condition, an expanded condition, and a length in the collapsed condition between a first end and a second end, the method comprising:

assembling the valve around a balloon having a fully inflated condition and a deflated condition, the balloon extending in a longitudinal direction and having a first tapered end portion, a second tapered end portion and a middle portion between the first tapered end portion and the second tapered end portion, the balloon having an outer surface and first and second retainer structures attached to the outer surface of only the middle portion and each of the first and second retainer structures defining a raised edge relative to the outer surface of the middle portion, the raised edges being spaced apart in the longitudinal direction to define a receiving space between the first and second tapered end portions, the first retainer structure is of a first type to accommodate a first end of the stent and the second retainer structure is of a second type different from the first type to accommodate a second end of the stent, the receiving space having a length in the longitudinal direction which is greater than the length of the stent structure in the collapsed condition, the valve being assembled in the receiving space so that the stent structure is in the collapsed condition and the balloon is in the deflated condition;

covering the valve in the collapsed condition and the balloon in the deflated condition with a sheath;

moving the covered valve and balloon to an implantation site;

removing the sheath from over the valve and the balloon to expose the valve and the balloon, whereby the valve is held in the receiving space and the raised edges allow for limited movement of the stent structure in the collapsed condition in the longitudinal direction relative to the balloon;

inflating the balloon to the fully inflated condition, whereby the stent structure of the valve is expanded to the expanded condition and the raised edges continue to limit movement of the stent structure in the longitudinal direction relative to the balloon, the raised edges being configured to maintain their shape while the balloon is inflated to the fully inflated condition;

after inflating the balloon to the inflated condition, deflating the balloon in order to release the stent structure from the receiving space so that the raised edges no longer limit movement of the stent structure in the longitudinal direction relative to the balloon; and

removing the deflated balloon from the stent structure.

10. The method of claim **9**, wherein removing the deflated balloon includes withdrawing the retainer structures through a lumen of the stent structure.

11. The method of claim **9**, wherein the first retainer structure is of a type selected from the group consisting of a node, a ring, a skirt, and a fan skirt.

12. The method of claim **9**, wherein the second retainer structure is of a type selected from the group consisting of a node, a ring, a skirt, and a fan skirt.

13. The method of claim **9**, wherein the raised edges are configured to allow for rotational movement of the stent structure in the collapsed condition.

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